REMARKS

This application has been amended in a manner that is believed to place it in condition for allowance at the time of the next Official Action.

Claims 28-32 and 37-45 are pending in the present application. Claims 28-32 have been amended to address the formal matters raised in the outstanding Official Action. New claims 37-45 have been added. Support for new claims 37-45 may be found in original claims 36 and 32.

In the outstanding Official Action, claims 28-32 were rejected under 35 USC §112, first paragraph, for allegedly not satisfying the written description requirement. In imposing the rejection, the Official Action alleges that one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises an "analogue of β-casomorphin-9" and "precursor of β-casomorphin 9". However, this rejection is respectfully traversed.

The Examiner's attention is respectfully directed to claim 28, which now recites that the immunomodulating component is selected from the group consisting of beta-casomorphin 9, beta-casein A2, and mixtures thereof. As the claimed immunomodulating component is directed to β-casomorphin-9 and β-casein A2, applicants believe that the rejection has been obviated.

Claims 28-32 were rejected under 35 USC §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

Claim 28 was rejected for reciting the terms "an analogue of β-casomorphin-9" and "precursor of β-casomorphin 9". However, these terms are no longer recited in claim 28. As a result, applicants believe that claim 28 is definite to one of ordinary skill in the art.

Claim 32 was rejected for reciting the term "population". However, while applicants believe that the term may be broad, applicants believe that the term is definite to one of ordinary skill in the art. Indeed, applicants believe that this is evidenced by the fact that the Office Action readily identifies several embodiments that can be used to characterize a population within the scope of the claims.

Thus, in view of the above, applicants believe that the claimed invention is definite to one of ordinary skill in the art.

Claims 28-32 were rejected under 35 USC §103(a) as allegedly being unpatentable over MEISEL et al. in view of KAFRISSEN et al. as evidenced by YUNDEN et al. This rejection is respectfully traversed.

MEISEL et al. teach that β-casomorphin-7 modulates blood pressure by inhibiting an angiotensin converting enzyme (ACE). Since ACE is a multifunctional enzyme, it is suggested that exogenous ACE inhibitors derived from casein may affect different regulatory systems involved in blood pressure (and implicitly, cardiovascular disease). As a result, the Office Action alleges that it would be obvious to equate this teaching to β-casomorphin-9 because β-casomorphin-9 is an "analogue" of β-casomorphin-7.

However, as noted above, the claimed invention is directed to β-casomorphin-9 and β-casein A2. β-casomorphin-7 is a distinct proteolytic peptide. β-casomorphin-7 is derived from β-casein A1 protein, whereas β-casomorphin-9 is derived from β-casein A2. The difference is caused by a nucleotide polymorphism at position 200 in the β-casein gene (adenine is replaced by cytosine). The resulting protein includes a histidine at position 67 (β-casein A1) instead of proline (β-casein A2), giving rise to different proteolytic peptides following digestion of β-casein in the gut.

MEISEL et al. also disclose that β-casokinin-10 modulates blood pressure by inhibiting the ACE. While β-casokinin-10 is a synthetic decapeptide, β-casokinin-10 is also a distinct peptide from β-casomorphin-9 or β-casein A2.

KAFRISSEN et al. fail to disclose or suggest a composition containing β-casomorphin-9 or β-casein A2. YUNDEN et al. studies conditions for the release of β-casomorphin-9 from bovine B-casein by gastrointestinal proteases. However, YUNDEN et al. fail to disclose or suggest a nutritional composition containing i β-casomorphin-9 or β-casein A2.

As a result, applicants believe that KAFRISSEN et al. and YUNDEN et al., alone or in combination, both fail to remedy the deficiencies of MEISEL et al.

Thus, applicants do not believe that it would be obvious to a person skilled in the art, based on the teaching of MEISEl et al. in view of KAFRISSEN et al., and as evidenced by YUNDEN et al. to predict that β-casomorphin-9 would have the same ACE inhibitory activity as β-casomorphin-7 or β-casokinin-10 for that mater.

Thus, in view of the above, applicants believe that the proposed combination of publications fails to render obvious the claimed invention.

In view of the present amendment and the foregoing remarks, therefore, applicants believed that the present application has been placed in condition for allowance at the time of the next Official Action, with claims 28-32 and 37-45, as presented. Allowance and passage to issue on that basis are respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. §1.16 or under 37 C.F.R.§1.17.

Respectfully submitted,

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PD/mjr

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